SEP 2 5 1998

K982300

510(k) Summary

Date:	June 15, 1998
Submitter's Name: **Submitter's Address:**	Toshiba America Medical Systems, Inc. P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Donelle Krajewski, Regulatory Affairs Specialist, (714)730-5000, Extension 4121
Device Proprietary Name: **Classification Name:** **Common Name:**	TRANSVIEW (Transmission System), Model NDTR-701A Emission Computed Tomography System Gamma Camera Option [Fed. Reg. No. 892.1200, Pro. Code: 90 KPS]
Predicate Devices:	ADAC Vantage (K943596), Picker STEP 2000 Option (K960865), Siemens E CAM Profile (K963983), and Elscint TransACT (K952674)
Reason for Submission	New option for existing product

Description of this Device:

The TRANSVIEW (Transmission system), model NDTR-701A is an option designed to be used with Toshiba's GCA-7200 gamma camera systems to acquire transmission CT data (TCT). When the external flood source of this system is combined with a parallel-hole collimator, this system can generate anatomic frame attenuation maps and perform attenuation corrections on SPECT images.

Summary of Intended Uses:

The purpose of this option is to provide non-uniform attenuation correction, simultaneously or sequentially, using a uncollimated sheet line source and a parallel-hole collimator. Toshiba America Medical Systems, Inc. believes that this device is safe and effective in that it offers no new intended uses that are not in use on existing marketed devices.

Technological Characteristics:

This device employs the same technological characteristics as the predicate devices, differing only in the specifics of subassembly component composition and algorithms used. All systems employ the use of a transmission source to provide the attenuation map. This attenuation map is then used to perform attenuation corrections on SPECT images along with scatter correction. Non uniform attenuation correction using transmission systems is well understood and is documented in peer reviewed scientific publications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

Donelle Kajewski
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
P.O. Box 2068
Tustin, CA 92781

Re: K982300
TransView (Transmission System),
Model NDTR-701A
Dated: June 15, 1998
Received: July 1, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Kajewski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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REGULATORY AFFAIRS

510(k) Number (if known):_____

Device Name: TRANSVIEW

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	YES	NO	Energy Range (keV)
A. Planar imaging	___	X	_____
B. Whole body imaging	___	X	_____
C. Tomographic imaging (SPECT) for non Positron emitter	X	___	50-400
D. Positron imaging by coincidence	___	X	_____
E. Positron imaging without coincidence	___	X	_____

F. Other indication(s) in the device label, but not included in above list _____

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Bryan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K982350